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Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE:

Docket No. 97N-484S

Gentlemen:

It has been brought to my attention that there is a proposal for FDA regulation of allograft as medical devices. This clearly does not make any medical sense. Please do not approve this proposal.

As an orthopedic surgeon using allograft bone for spinal fusions, I do think that this would not be a proposal that makes any medical sense.

Very truly yours

AMS/ds

Arnold M. Schwartz, M.D.

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